



UNIZA LIFECARE PRIVATE LIMITED

OLD S.R NO 404,SR.NO 919 KADI-DETROJ ROAD BALASAR KADI - 382715

QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT, 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name	: CLOTRIHEAL CREAM 30GM	A.R. No.	: 7/4/0912
Packing	: 30 Gram	Release Dt.	: 27-11-2024
Generic Name	: Clotrimazole Cream IP	T.R. Slip No.	: ULPPTR24250389
		T.R. Slip Dt.	: 21-11-2024
Product Code	: 700176	Mfg. Dt. :	11/24
Batch No.	: 40877	Exp. Dt. :	10/26
Actual Batch Size	: 300.0000 kg	Test As per :	IP
Sample Size	: 450.000 Gram	Specification No. :	FPS/OIN/0069/00
Released Qty.	: 299.8800 kg	STP No.	: UNF/MOA/0253 /00
		Mfg. Lic. No.	: G/25/2489
		Location	: KADI
		Company	: UNIZALIFE

Sr. No.	Test	Result	Specification
1.00	Description	A white colour smooth cream filled in laminated tube.	A white to off white colour smooth cream filled in laminated tube.
2.00	Identification	.	.
2.01	By HPLC	Complies	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in the assay.
3.00	Minimum filling	30.01 gm	Not less than 30.0 gm
4.00	Homogeneity: (By Visual)	Complies	No visible particles detected in 3 of 4 sample.
5.00	Leakage test: (At 45°C ±3°C for 8 hrs)	Complies	No cream leakage detected.
6.00	2-Chlorotritanol (Impurity A)	Not Detected	NMT 1 %
7.00	Assay	.	.
7.01	Clotrimazole IP.....1.0 % w/w	1.0084 % w/w 100.84%	Between 90.0 % to 110.0% of the label claim.
7.02	Methyl Paraben IP....0.15 % w/w	0.1564 % w/w 104.27%	Between 90.0 % to 110.0% of the label claim.
7.03	Propyl Paraben IP....0.05 % w/w	0.0520 % w/w 104.00%	Between 90.0 % to 110.0% of the label claim.
7.04	Benzyl Alcohol....1 % w/w	1.0023% w/w 100.23%	Between 90.0 % to 120.0% of the label claim.
8.00	Microbial Contamination	.	.
8.01	Total aerobic microbial count	Less than 10 CFU/g	Not more than 1000 CFU/g.
8.02	Total yeast and mould count	Less than 10 CFU/g	Not more than 100 CFU/g.
8.03	E.Coli	Absent	Should be absent

Prepared By	Checked By	Approved By
JAYENDRA PATEL	RAKESHBHAI PATEL	MANOJ PATEL
QC EXECUTIVE	ASSIS. MANAGER	QC MANAGER

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FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Sr. No.	Test	Result	Specification
8.04	Salmonella	Absent	Should be absent
8.05	Pseudomonas aeruginosa	Absent	Should be absent
8.06	Staphylococcus aureus	Absent	Should be absent

Conclusion : The above sample complies as per IP. "This computer generated certificate of analysis is valid without signature"

Prepared By	Checked By	Approved By
JAYENDRA PATEL	RAKESHBHAI PATEL	MANOJ PATEL
QC EXECUTIVE	ASSIS. MANAGER	QC MANAGER

Note : "Report is computer generated,does not required signature"

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